Pharmaceutical information; a 30-year perspective on the literature

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Abstract

The literature describing the pharmaceutical information is reviewed, from 1980 (with some earlier material included) to 2008. The review, with 466 references covers: the pharmaceutical information domain; previous reviews and monographs; pharmaceutical information producers and users; pharmaceutical information organisation (classifications, thesaurus and terminoloigies); pharmaceutical information sources, services and retrieval; pharmaceutical information and knowledge management; and the domain's influence on the information science discipline.

The review shows the pharmaceutical subject domain to be particularly information intensive, with a complex communication chain, involving a notably varied set of producers and users of information, and a rich and diverse set of resources. The area has seen much pioneering work in the development of information systems and services, and of the management of information and knowledge. It can reasonably be argued that it stimulated and nurtured the development of information science as a discipline.

Introduction

This article provides a selective review of the literature of pharmaceutical information since 1980 to the end of 2008, with a few significant earlier and later papers included. This relatively long time period is justifiable, since there are no previous substantive review articles on the topic. It also allows a historical approach to be taken, showing developments over time, and highlighting those aspects which have remained relatively constant. References are therefore cited from across the whole of this time period.

The article relies on published literature, mainly journal articles and mainly English-language. With a very few exceptions, web resources have not been included, because of their ephemeral nature. The material was identified from the authors' own resources, supplemented by searching of bibliographic databases – Library and Information Science Abstracts, Medline and Web of Science – and by following up citations.

The intention is not to provide anything like a comprehensive coverage of a voluminous literature, but rather to illustrate the unique nature of pharmaceutical information, and the ways in which its development has influenced a wider area of information science. Particular sources are mentioned as exemplars; this review is not intended to serve as a resource guide, although pointers are given to such listings.

The focus is on information sources, systems and services, and on information and knowledge management. Information technology, information systems and informatics aspects – which form a large literature in their own right for pharmaceuticals – are mentioned only when of direct relevance to our main focus. Where there is literature relating to information functions, resources and so on, in a variety of environments, only that referring directly to the pharmaceutical environment is cited.

The structure and content of the review draws from the ideas of 'domain analysis' (Hjørland 2002), whereby distinct approaches, of which Hjørland originally noted eleven, may be used to help to understand the information of a domain. The aspects used here, in respect of pharmaceutical information, are:

- nature and structure of pharmaceutical information
- existing literature guides and subject gateways
- special classifications, taxonomies and thesauri
- specialist terminologies
- resources, indexing and retrieval
- user studies
- structures and organisations in the communication of information
- historical studies

The review, following this introduction, is divided into sections:

- the pharmaceutical information domain
- previous reviews and monographs
- pharmaceutical information producers and users
- pharmaceutical information organisation; classifications, thesauri and terminologies
- pharmaceutical information sources, services and retrieval
- pharmaceutical information and knowledge management
- influence on information science
- conclusions

The pharmaceutical information domain

'Pharmaceutical information' is usually taken to mean all the information required for, and produced during, the discovery, development, production, supply, regulation and use of medicines. Usually, human medicines are meant, though the term may sometimes also cover information relevant to veterinary medicines. The term usually includes all 'remedial preparations', and hence covers vaccines, antisera, diagnostics, etc.

The terms 'medicines information' and 'drug information' have been used synonymously, although the latter has, in recent years, mainly taken the meaning of information provided relating to the use of recreational drugs.

Gagnon (1986), in fairly typical view, considered the area to comprise five disciplines: medicinal chemistry; pharmaceutics; pharmacology and toxicology; pharmacy administration; and pharmacy practice.

The educational philosopher Paul Hirst argues that, since disciplines are closely associated with their knowledge base, we can understand a discipline by understanding its "form of knowledge" (Hirst, 1974, Hirst and Peters,1970). Hirst identifies seven main domains or forms of knowledge, defined by the fundamental nature of the knowledge and concepts with which they deal: mathematics, physical sciences, human sciences, literature and the fine arts, morality, religion, and philosophy. Where a discipline equates to one of these forms, it is what would be regarded as a “pure” academic subject.

Hirst also recognises “practical disciplines”, based on one of the forms, but oriented toward solving practical problems. Pharmaceuticals, in his terms, would be, like all the other biomedical disciplines, a practical discipline based on the form of knowledge of the biological sciences. Like other healthcare topics, however, it also includes materials more related to the social sciences (Robinson 2010).

We may expect therefore that pharmaceutical information will be of diverse nature, but will follow healthcare knowledge in having a generally clear and consistent structure, in the form of a complex hierarchy, with many levels (Blois 1984, 1988, Patel and Kaufman 2000, Robinson 2010). This is confirmed by the nature of pharmaceutical information resources, and information organisation, discussed below.

Pharmaceutical information is created and used by a wide variety of groups, including:

- scientists in academia and in the pharmaceutical industry
- industry marketers, government regulators, and health service purchasers and managers
- doctors, pharmacists and other healthcare professionals
- the general public, as 'consumers' of prescription and over-the-counter medicines

Information about medicines is extensive and very varied in its nature and its intended use and users. Information is produced, and required, at all stages of the development and use of medicines, from the earliest stages of multidisciplinary pharmaceutical R&D, through clinical trials and regulatory approval, through the use of medicines on prescription and sold over-the-counter (see, for example, Brown 1983, Haygarth-Jackson 1987A, Robson, Bawden and Judd 2001). Kasarab (2006) notes one practical consequence of this - the need for very extensive document supply services for a pharmaceutical company. As early as 1963, a National Library of Medicine survey on drug literature commented that "Drug literature is vast and complex. The very problem of defining what constitutes the literature is difficult… It is also increasingly complex, i.e. interdisciplinary and interprofessional in nature. Thus, drug information 'sprawls across' many professional journals of the most varied types" (Gora-Harper and Amerson 2006). The situation has not changed in the intervening half-century.

The 'scientist' information producer/user group is a very broad one. Pharmaceutical information is of relevance not only to those sciences which focus on the topic – pharmacy, pharmacology, toxicology and medicinal chemistry – but also to a range of associated sciences, including:

- chemistry, particularly synthetic and analytical chemistry
- biosciences, including biochemistry, molecular biology, genomics, bacteriology and virology
- medicinal sciences and medicinal practice, including public health and epidemiology

The economic and social importance of pharmaceuticals, and the pharmaceutical industry has led to the need for extensive 'pharmaceutical business' information on markets and competitors. The intensive regulation of the industry, and concerns about the safety of medicines, has led to extensive information systems in support of the regulatory function, and also in support of pharmacovigilance, to identify side-effects of drugs.

Recent moves towards 'consumer health information' have led to a greatly increased need for the provision of pharmaceutical information directed to patients, carers and other concerned members of the public, particularly through the increasingly important medium of the Internet.

This breadth of scope, plus its economic and social importance, lends pharmaceutical information a unique place within information science, with a particularly rich set of information resources, and tools and systems for information handling. The pharmaceutical industry, in particular, is often referred to as the original "information intensive industry" (Haygarth-Jackson 1987A), and as an industry aware of the power of information (Nielsen 1996), and that "information is the lifeblood of the research based pharmaceutical industry". (Sherwell 1997A). In 1980, Hyams identified it as one of three "information conscious industries" (the others being aerospace and food), while Brown (1985) considered the past and future of the "information facets" of a new drug from a perspective in the 1980s, and Snow (2008) gave a picture of the extensive communication aspects of the drug development process thirty years later. As a consequence of this, particularly large investment has been made in information systems and services (Di Nalol and Schopfel 2008), sometimes with the explicit aim of creating an "information rich environment" (Bawden 1986); see also Lamb, Kling and Kling (2003). "The [pharmaceutical] industry", wrote Pickering (1990B, page 3), "spends very freely on information handling". This free spending, and that of health services and regulators, has provided the range of specialised and innovative services that mark this subject out in information terms (Sillince and Sillince 1993). Although the matter is controversial, there is some evidence that more "information aware" companies show greater research productivity (Koenig 1990).

The pharmaceutical domain has often pioneered new forms of information systems and resources, influencing the development of information science and information management more generally. These developments have been promoted by specialists in pharmaceutical information, working within the pharmaceutical industry, health services, and professional institutions.

The nature of the pharmaceutical information domain, which is the focus of this review, is formed by the context in which this information is produced and used. This context has changed greatly over the time period of this review. Some of the cause for changes are directly 'information service related', for example the almost total replacement of printed journals and reference works by electronic equivalents; these are dealt with in the appropriate places later. Changes in the environment are also of significance. Among the more important, six major and continuing clusters of changes can be identified.

The first is the continuing consolidation of pharmaceutical companies into multinational 'big pharma': see, for example, Spilker (1989), Guay (1988), and Koenig and Mezick (2004). This has had direct consequences in a need for 'global' information provision, and for the merging of services: see, for example, Schwartzer (1995), Riggins et.al. (1999), Marsh (2000), Robson and Riggens (2001), Culley, Hoffman and Slavik (2000), Di Nallo and Schopfel (2008). Similar information-related issues arise from the creation of 'alliances' of separate companies (Whitehead, Lomma, Tran Miao and Pikalov 2009).

The second is the increasing focus of pharmaceutical research on continuous innovation, cost cutting and on shortening development times: see, for example, Kennedy 1997), Again, this

has information consequences – see, for example, Skaug (1995), Abbott (1998), Steven (2002), and Gassman, Repmeuer and von Zedtwitz (2004).

The third is the changing nature of the science carried out in pharmaceutical research, with small molecule synthesis and testing complemented and replaced by methods from molecular biology and genomics, and high throughput screening. Again, this has consequences for the type of information generated and needed – see, for example, Ward and Warr (1998), Cole and Bawden (1996), Ohlstein, Ruffolo and Elliott (2000), Cunningham (2000), Fischer and Heyse (2005), Kshirsager (2008).

The fourth is changes in health service requirements and expectations for the provision of medicines, particularly to address the problems of ageing populations, and chronic diseases: see, for example, Avgerou, Cornford and Mossialos (1996), Andersen, Rice and Kominski (2007) and Tovey (2000).

The fifth is the increasing emphasis, noted above, on consumer health information and hence greater need for pharmaceutical information for the general public (Shulman 1988, Gann 1987, 1991, Cline and Haynes 2001, Abbott 1998).

The sixth involves information technology, and in particular the advent of the Internet, which has changed the information practices of consumers and professionals in a remarkable way (Johson and Wordell 1998, Dupuits 2002). Commenting on this, in their monograph on drug information, Malone, Kier and Stanovich (2006 page xxiii), note that "the impact of the Internet can be seen in this book. The first [1996] edition contained only two pages of information about the Internet [but] in this new [2006] edition, it seems as if hardly a page can be found without some reference to Internet material".

But even apart from the Internet, the change in the technological environment has been profound, and, as will be discussed later, led in large measure by the pharmaceutical information sector. Just prior to the period covered by this review, a pharmaceutical company reported the replacement of its card catalogue database by a punched card system (Bird 1976), One of the authors of this review can recall as a trainee in a pharmaceutical information department having to carry out a search through in-house database reflecting the industrial archaeology of information retrieval: card indexes, edge-notched cards, optical coincidence cards, punched cards, and finally computer files. The changes in the technologies of information have had perhaps the most dramatic effect on pharmaceutical information provision, but must be considered in conjunction with the other changes.

These environmental changes over three decades form the backdrop to this review.

Previous reviews and monographs

The literature of pharmaceutical information is extensive. A search of the Library and Information Science (LISA) bibliographic database for the term 'pharmaceutical' (a far-from-comprehensive search strategy in a far-from-complete data source) returns over 1600 journal articles and published conference papers between 1980 and 2008.

There is one journal wholly devoted to the topic: *Drug Information Journal*, published quarterly by the international Drug Information Association since 1967. Apart from this source, articles are scattered across a wide variety of journals, largely in library and information science and information management, but also in journals of information systems and informatics, pharmacy, pharmacology and medicine.

Despite this plethora of primary materials, reviews and monographs are scarce.

No previous ARIST review has focused on pharmaceutical information, although the topic is mentioned in reviews on medical, chemical and toxicological information. Nor are there any substantive reviews of the whole area in other sources, although there are numerous summaries of sources and services, typically rather short and ephemeral; as an example of the more thorough of these, see Calam 1992 .

There have, however, been a number of monographs produced over the period from 1980 to 2008, acting in effect as extended reviews. Several of these will be described, so as to exemplify differences in approach and coverage, and changes over time.

In the monographs produced throughout the 1970s and 1980s, 'pharmaceutical information' was taken as largely synonymous with 'the literature of pharmacy'. Good examples of this approach are Sewell (1976), Andrews (1986), and Strickland-Hidge, Jepson and Reid (1989). The first of these was aimed primarily at pharmacy students and practitioners, the second at librarians, the third at librarians and information workers, indicative of the extent to which this area was becoming an important field within information science during this period. They are essentially annotated lists of sources, largely printed although some computerised sources are mentioned, and emphasising the significance of specialist libraries and other information suppliers. All stick fairly closely to the 'pharmacy' remit, though both Sewell and Andrews include some materials on associated areas; chemistry, pharmacology, toxicology and medicine.

An early example of a monograph taking a wider viewpoint is a volume in the Butterworth / Bowker Saur series of 'Information Sources …' guides, which aimed at a 'library/information' audience, and covered pharmaceutical information to the end of the 1980s (Pickering 1990). Focusing, in accordance with the series aims, on information resources, this extensive (566 page) guide took, for the most part an industry perspective. Its 20 chapters were divided into three sections. The first section, dealing with information resources in detail, had chapters covering: chemical and physicochemical information; biologicals and biotechnology information; biological and biomedical information; toxicology and drug metabolism information; technical development and product information; intellectual property; marketing and business information; legal and regulatory issues; and post-marketing experiences. The second section, dealing with the institutions and organisations providing pharmaceutical information, had chapters on: publicly information drug information from a variety of sources; the industry as a source of information; and the World Health Organisation. The third section, dealing with the variability of provision of pharmaceutical information in various regions of the world, covering the USA, Western Europe, Japan, Australia, South America, Central Africa and China.

Pickering's book sums up well what we might call the classical picture of pharmaceutical information, just before the changes brought about by restructuring in the industry and in healthcare provision, and by the Internet. It is a picture of a wide range of sources, printed and computerised, and a wide range of providers, though with use largely restricted to professional groups; general public access is mentioned in only one chapter. The issues of a

'pharma information divide' between rich and poor parts of the world looms large, and has been a continuing theme; see, for example, Pakenham-Walsh, Edleston and Kaur 1999.

A more recent example is a book intended to accompany a UK Masters course in pharmaceutical information management, and aimed primarily at those working in pharmaceutical information functions in industry and the health service (Robson, Bawden and Judd 2001). Its substantive chapters covered: information sources; information technology; information and knowledge management; provision of information; analysis and evaluation of information; professional and managerial skills; medicines information in the UK health service; medical information services in the pharmaceutical industry; research information in the pharmaceutical industry; commercial information; pharmacovigilance; regulatory affairs; document and records management; end-user support and training; and codes of practice and ethics. These topics emphasise the wide scope of the topic, and illustrate the overlaps between pharmaceutical information *per se* and more general information science and information management.

A further example, typifying a number of 'Pharmaceutical Information for ….' monographs aimed at particular professional groups, and following in the mould of the earlier monographs mentioned above, though with a considerably wider scope, is the third edition of a guide for pharmacists and pharmacy students (Malone, Kier and Stanovich 2006). Its eighteen chapters cover: concept of medication information; systematic approach to answering questions; effective responses and recommendations; drug information resources; electronic information management; clinical trial evaluation; literature evaluation; pharmacoeconomics; evidence-based practice; statistical analysis; professional writing; legal responsibilities; ethical issues; pharmacy and therapeutics committees; drug evaluation monographs; quality issues; adverse reactions and medication errors; and drug information through the licensing process. Again we see the overlap between the core of pharmaceutical information – information resources and the handling of information – and more general information-related activities, appropriate to a healthcare profession.

The last of the exemplar monographs, the third edition of a well-known guidebook, is a comprehensive and detailed resource guide aimed primarily at librarians and other specialised information providers (Snow 2008). Chapters cover: drug identification; government regulation and its information consequences; literature searching and evaluation; sources in pharmacology and therapeutics; sources for adverse reactions and drug interactions; sources for formulation and analysis; competitor intelligence resources; and business information sources. Emphasis is placed on choice of the best combination of sources, from an increased range and diversity, commonly now available in digital, and specifically web-based, formats.

These examples of monographs reviewing the pharmaceutical information area show two clear movements over time. The first is from a restricted 'pharmacy based' viewpoint to a much broader subject domain. The second is a much wider range of resource types, largely brought about by the increased availability and diversity of digital information sources. They also illustrate the increasing recognition of pharmaceutical information as a specialism within information science.

Pharmaceutical information producers and users

It will be clear from what has been written above that the communication chain for pharmaceutical information is complex, and involves an unusually large number of types of participant. They include academic and industrial research scientists and clinical researchers, healthcare professionals (particularly doctors and pharmacists), government regulators, pharmaceutical industry information units (typically categorised as research, medical or commercial), consumers (mainly patients, carers and support groups), and librarians, publishers and database producers (Robson, Bawden and Judd 2001).

Typically, all these are both users and producers of pharmaceutical information; even patients, who have hitherto been assumed to be passive consumers of information on the medicines which they use, are now generating information, both through formal channels, for example communicating experiences of side-effects (Craigle 2007), and through informal channels, usually internet-faciliated such as blogs, forums and newsgroups.

To help discussion of these issues, we will adopt an extremely over-simplified model, regarding the life-time of a medicine in three stages: discovery and development; regulatory approval; and use of medicines. We will, necessarily, restrict the discussion to those aspects where clear 'information consequences' have been discussed in the literature in the period reviewed.

Stage 1: Discovery and development

The first stage is that in which medicines are discovered and developed, to the point where an application can be made for their widespread use, either on prescription through a medical practitioner, or sold 'over the counter' direct to the public.

Information users and producers here are primarily scientific and clinical researchers, in academia and in industry; the wide variety of disciplines involved has already been noted. Other participants at this stage are those involved in assessing viability of new medicines, whether in scientific areas such as epidemiology or in business areas such as marketing and competitor intelligence.

Studies of the information practices of research scientists have been widespread over several decades, to the extent that it could be said that information user studies until the mid-1980s were in fact studies of scientists' information behaviour (Wilson 1984): for overviews, see Case (2007) and Tenopir and King (2002). A proportion of such studies over the years has focused on scientists involved in pharmaceutical research, in both academic and industrial settings: see, for example, Ash et.al. (1985), Ljungberg and Tullgern (1977), Brown (1984), Charton (1992), Rolinson, Meadows and Smith (1995), Rolinson, Al-Shanbari and Meadows (1996), Bawden, Devon and Sinclair (2000). These studies have shown, in broad terms, that pharmaceutical research scientists share the information behaviour patterns of scientists in general, but with an added requirement for diversity of information from a wide variety of sources, and a particular enthusiasm for using new technological aids. This reflects the diverse nature of the pharmaceutical information domain, and the perceived requirement, and availability of funding, for the latest technical solutions.

In many respects, the information needs and practices of, and sources useful to, scientists in these early stages of pharmaceutical research are the same as those chemical and biomedical scientists in other environments. This review cannot cover all of these issues, nor mention all of these sources; it focuses on specific pharmaceutical issues and applications.

Communication of information at this stage is facilitated by the usual infrastructure of scientific libraries and information services. For the pharmaceutical domain specifically, these include:

- specialist pharmaceutical libraries (see, for example Strickland-Hodge, Jepson and Reid 1989 chapters 2.1 and 2.2, Bador, Locher and Gallezot 1991, Ottlik 1992, Lapidus 2003, Knoben, Phillips and Szczur 2004, and Knoben et al. 2004), including those in industry (see, for example, Haygarth-Jackson 1977, Schultze 1986, Dieckmann and Whittall 1998, Sandori 1992, and Sherwell 1997B). Such libraries are increasingly wholly digital in nature.

- specialist library networks, which may include both academic and industrial libraries (see, for example, Willaims, Bliven and Ladner 1987)
- pharmaceutical, and other biomedical, data services (see, for example, Mendelsohn 1999)
- pharmaceutical database producers and publishers (see, for example, Fowler 2001, Lyon, Warr and Brown 1996 and Felter 2005).

It is usually the case that information at this early stage in the life of medicine is communicated only to researchers and health professionals. However, the pressure for information to be widely communicated has led to initiatives to provide information to potential users of new medicines at an early stage; for example, publicly accessible databases of clinical trials of new drugs (Mi 2005, Antonelli and Mercurio 2009).

Within the pharmaceutical industry, provision of information at this stage this is largely the remit of the 'research' or 'technical' information services (Haygarth-Jackson 1977, Nelson 1989, Pay 1991, Goodman, Whittall and Morrison 2001). These departments have an inward focus, their main task being to provide information services to R&D staff within the organisation. This may, in turn, cover a wide scope of subject matter, from the purely scientific to information on markets and competitor activities. The traditional role has been that of the 'intermediary', carrying our searches and providing current awareness (Bawden 1986), based largely on the scientific literature. With the advent of online systems aimed at the end-user Leipzig, Kozak and Schwartz 1983, Mullan and Blick 1987, Warr and Haygarth-Jackson 1988), and particularly of web-based services, this has largely been supplanted by one of promoting user access, resource provision, database creation, and training and consultancy (Goodman and Boyce 2001).

Another important function of research information departments has been the maintenance of databanks of internally generated information (Goodman, Whittall and Morrison 2001, McTaggart and Radcliffe 1977). Here, there is increasing overlap with provision of bioinformatics and chemoinformatics systems and services (Cole and Bawden 1996).

The pharmaceutical research information function has also shown most strongly the changing balance between the perceived merits of the 'information professional' provider in an information department, and the 'information liaison' function, embedded in scientific teams: see, for example, Sze (1985).

While most of the information provided by, or through, research information departments is strictly scientific in nature, two other important areas impinge on their work, and may be handled by staff within the information unit, or in conjunction with specialist departments.

The first is competitive intelligence, an essential issue for a particularly competitive industry (Desai and Bawden 1993, Krol, Coleman and Bryant 1996, Bawden 1998, Bexon, Stephens and Pritchett 2002). This function is located variously in different organisations, with the information department taking different roles. It is characterised by a need to access a very wide variety of sources, from science through business to news, and including numerous databases specifically created to serve this function (Mullen et al. 1997, Blunck et al. 2003).

The second is the handling of intellectual property, in particular patents; these latter having always been of great importance to the pharmaceutical industry both for their importance as scientific information resources, as well as indicators of competitor activity (Nolan, Oppenheim and Withers 1980, Eisenschitz 1990, Correa 2004, Yoo, Ramanathan and Barcelon-Yang 2005). Again, the information department may play various roles *vis a vis* intellectual property specialists, and again a variety of specialised resources are available (Goodman, Whittall and Morrison 2001, Wilson 2007). Pharmaceutical patents may also be important information sources for information providers outside the pharmaceutical industry (Hogan and Scarborough 1996).

Stage 2: regulatory approval

In this stage, when a new medicine has been shown in clinical trials to be safe and effective, approval is needed from national and international regulatory bodies, before it is permitted to be used routinely (Griffin and O'Grady 2003, Snow 2008). Further approvals may be needed before it is recommended for use by national health services, and still further local approvals may be needed before it is included in a hospital formulary or local approved drugs lists. Legal frameworks, and the nature of regulatory agencies, differ in different countries, although international harmonisation is increasing, particularly within the European Union. Among the best known and most influential of the regulatory agencies are the U.S. Food and Drug Administration, the E.U. European Medicines Agency, and the U.K. Medicines and Healthcare products Regulatory Agency, and National Institute for Health and Clinical Excellence. Each country has its own equivalents.

This process of approvals, which may generate public controversy, is highly information-intensive (see Snow 2008, for a detailed discussion of information products and services with respect to regulation; see also Beglin 2001, Zimmer 2003 and Goldwire and Rumore 1993). The regulatory agencies are major consumers of information, analysed and evaluated in order to reach decisions and make recommendations (see, for example, Britt 1996), and also major producers of data collections, guidelines, etc., which are in themselves important sources of pharmaceutical information throughout the lifetime of the medicine. Consistent international terminology is of obvious importance. The MedDRA (Medical Dictionary for Regulatory Affairs) vocabulary has been developed for this purpose, drawing terms and concepts from existing vocabularies such as WHO-ART (World Health Organization Adverse Reaction Terminology), COSTART (Coding Symbols for a Thesaurus of Adverse Reaction Terms) and the International Classification of Diseases (West 2001, Doan 2002, Tucker 2002, Kubler 2005, Brown, Wood and Wood 1999).

The need for pharmaceutical companies to process and prepare very extensive sets of information for regulatory approvals has led to innovation in a number of areas, including records management (Pease 1995), content management (Michalak et al. 1996, Agoratus 1999) including a move to fully digital regulatory submission (Attridge 2005), and technical writing (Bonk 1998).

Stage 3: marketed medicines

When a medicine enters general use, copious information is produced and used throughout its life; and indeed afterwards, since the information base on medicines no longer in use must be maintained in order to deal with the consequences of long-term adverse effects.

Users and producers of information at this stage are again diverse, and include healthcare professionals, academic researchers, government regulators, the pharmaceutical industry and the general public.

Health care workers, doctors and pharmacists in particular, must make extensive use of such information in order to use medicines correctly. They provide information primarily through the medical and pharmaceutical literature, and through systems for the reporting of adverse effects. As in the case of research scientists mentioned above, there have been numerous studies of the information-related behaviour of healthcare workers behaviour of doctors, pharmacists and other healthcare workers (Case 2007, Bush, King and Tenopir 2004, Stinson and Mueller 1980). Several studies have examined this behaviour as it relates to pharmaceutical information, most commonly for doctors and pharmacists in Western Europe and North America; see, for example, Joy, Arana and Gallo 1986, Simon et al. 1987, Abate, Jacknowitz and Shumway 1989, Liddell 1990, Koo and Miller 1992, Gaikther et al. 1994, Gerrett and Clerk 1997, Lundborg, Hensio and Gistafsson 1998, Medicine on the Net 2002, Coumou and Meijman 1994, Schrimsher, Freeman and Kendrach 2006, and Ko and Sklar 2009). They tend to show a general reliance on a small number of sources for pharmaceutical information: standard reference texts and formularies, colleagues, and pharmaceutical company representatives, joined now by Internet sources. 'Formal' sources, such as libraries, information centres, and bibliographic databases, have been relatively little used. The same is true for doctors and pharmacists in the developing world (Kreling and Dzvimbo 1989), and for

other healthcare workers having responsibility for medicines, including nurses (Wolfgang, Perri and Katzan 1989, Hittel and Yost 1981, Haymind, et al. 1977), dentists (Parker and Reid 1978, Murray 1981), and clinical research coordinators (Wessel, Tannery and Epstein 2006).

Pharmacists, in particular, have been recognised as having a 'gatekeeper' role, having an important role as both recipients and providers of medicines information (see, for example, Watt 1977, Vainio et, al. 2004); indeed, Byrd (2002) has suggested that pharmacy could be a model for a "health informationist" profession. Pharmacists provide drug information to a variety of recipients, in community practice, in hospitals and clinics, and in specialised medicines information services. These are operated by national health services, with the aim of providing information on medicines to doctors, pharmacists, nurses and other healthcare workers, and also to patients (Judd 2001, Hands et al. 1999, Smith 1987, Hibberd 1980). This may involve creation of centralised drug databases, input into creation of local formularies and prescribing policies, and assessment of new drugs, as well as advising on use of medicines for particular patients. Such services have been shown to have a direct and beneficial effect on patient care in providing information on adverse drug effects (Stubbington et.al. 1998), though evidence of more general impact is limited (Hands, Stephens and Brown 2002, Rutter, Brown and Rutter 2004).

Academic researchers and industrial clinical investigators continue to carry out research on marketed medicines, in order to study problems and to identify new opportunities for use. Government regulators monitor use of medicines, and provide updated guidelines on appropriate use; there may be separate versions of guidance aimed at health professionals and at consumers.

Regulators have a particular responsibility to maintain pharmacovigilance systems for identifying unwanted effects of medicines, enabling the assessment and prevention of side-effects. This process begins during the clinical development of drugs, and extends through post-marketing surveillance to identify and assess adverse drug reactions, through the time a drug is on the market, and indeed afterwards. It is a complex and information-intensive process, with numerous sources, regulations, legal issues, methods, and protocols (Medicines and Healthcare Products Regulatory Agency 2008, Mann and Andrews 2007, Talbot and Waller 2003).

There are numerous pharmacovigilance systems for capturing, coding, storing and reporting data and information on adverse effects of drugs, within government agencies, international organisations and pharmaceutical companies (Fucik and Edwards 1996, West 2001, Sakurai et.al. 1995, Fallowfield 1995, Soller 2004, and Bess and Umrath 2005). Sometimes these use standard vocabularies for indexing the data, although special coding schemes, such as the World Health Organisation's WHO-ART, COSTART and the newer MedDRA, may also be used, as for regulatory issues (Fizames 1997, Brown, Wood and Wood, 1999, Goldman 2002). This information is increasingly made available to the general public through the Internet (see, for example, Mani 2006).

The pharmaceutical industry also carries out many information related activities at this stage. It must have systems for pharmacovigilance, as noted above, and must identify information on the use of the company's products, and competitors, in support of sales and marketing. It also has the responsibility to provide information on its own products to prescribers and users, through medical information departments.

Pharmaceutical industry medical information departments have a two-fold role (Leighton and Davies 2009)Robson and Riggens 2001, Roach 1982, Royland 1982, Huntingford et, al, 1990, Robson and Robson 1990, Pay 1991, Yamamoto et.al. 1995, Robson et al. 1996, Hopkins, Galligher and Levine 1999). Internally, they provide information services to a variety of customers within their organisation, most particularly to the sales and marketing functions, but also to the medical and regulatory affairs departments. Externally - and the main reason for their existence - they provide information on their company's products to healthcare workers, particularly doctors and pharmacists. Although publicly available or externally produced sources may often be used by medical information departments, reliance is usually placed on 'in-house' databases of publications and other material on the company's products,

created and maintained by the department (Van Putte and Peperkamp 1983, Gretz and Thomas 1995, Hull 1996, Robson and Riggens 2001): as examples, see Ortelli and Ferrario (1990), Bauman and Bettenhausen (1994) and Gasperino and Lynn (1995). In some circumstances, such databases have been integrated with current awareness services (Hodge and Walker 1984).

To a limited degree and varying from country to country, in the case of prescription medicines information is provided to patients and the general public, backing up the patient information leaflets required with all medicines, and for which the best information content and presentation has been extensively debated (Brown 1989, Robson and Riggens 2001, Newton et al. 1998, Twomey 2001, Payne 2002, Smith and Ramseyer 2002, Gustafsson et.al. 2003) A perennial issue is the extent to which information provision from the industry overlaps with marketing and advertising, particularly where information provision to the public and to patients, and patients' organisations and support groups, is concerned (Herxheimer 2003, Young et.al. 2005). This is of particular importance, since sales representatives and marketing departments are among the most important users of medical information departments (Robson and Riggens 2001, Yamamoto et al. 1998. Baumen and Bettenhausen 1994). The sensitive nature of this kind of information provision is evidenced by a unique concern for deceitful enquiries; for example, by members of the public claiming to be medical practitioners, or by employees of competitor companies who do not identify themselves as such (Curran 2002).

Commercial information within the pharmaceutical industry is sometimes carried out by specialist units, sometimes as an activity of research or medical information units. It involves provision of a variety of business, financial and company information, with a particular focus on the competitor intelligence and environment scanning noted above, and is sometimes regarded as a specialism within pharmaceutical information (Desai and Bawden 1993, Berkien 2006, Snow 2008) .

The idea that the general public would have a need for information about medicines, or that it would be appropriate to provide such information to them, is of recent standing. Although information for the public about health and medical matters counts among the oldest writings, featured among the first output of the printing press, and has been a staple of publishers ever since (Robinson 2010), information about prescription medicines was felt to be a matter for the medical profession until relatively recently. None of the pre-1990 literature guides mentions it, but Barry in 1991 could write about "the desire of an increasingly sophisticated public to know about commercial drugs … patients know much more about drugs than they did even 10 years ago". The interest in the provision of information to the general public has increased dramatically, fuelled by the consumer health movement, and the availability of the Internet as a communications channel. We have noted above the provision of 'public-friendly' versions of regulatory guidelines, the opening up to the public of databases of clinical trials information and of pharmacovigilance data, and the tensions implicit in the desire of the pharmaceutical industry to provide information direct to the public, beyond that included in patient information leaflets. One way in which this is being achieved is through the medium of the web, emphasising education on diseases and treatments, rather than promotion of particular products (see, for example, Vigilante and Wogalter 2005, and Howe and Baker (2007), and through the support of patients' organisations, itself controversial as noted above (Herxheimer 2003).

Studies of the information-related behaviour of members of the public seeking pharmaceutical information show that this pattern is typical of those seeking any form of health information (Case 2007). A wide variety of sources are used, including books, magazines, newspapers, public libraries, radio and television, family and friends, support groups, and healthcare workers, but with the Internet now usually taking a major role: for examples, see Farmer and Peffer (1996), Trewin and Veitch (2003), Dutta-Bergman (2004), Cantrill et al. 2005. Nicholas et.al. (2007) and Keselman, Browne and Kaufman (2008).

Pharmaceutical information organisation; classifications, thesauri and terminologies

We have seen that pharmaceutical information is broad in scope and diverse in nature, with a wide range of resource types and users. It is natural that there will be a variety of intellectual tools for the organisation of pharmaceutical information.

The first type to be considered are library classifications, of importance for the organisation of printed material, and also useful with digital material. Sewell (1976) notes the Dewey Classification (DDC), the Library of Congress Classification (LCC), and the National Library of Medicine Classification (NLMC) as the three likely to be encountered in a pharmacy-related library in America. The same is like to have to been true anywhere in the world at that period, except for Continental Europe, where the Universal Decimal Classification (UDC) predominated. Strickland-Hodge, Jepson and Reid (1989) also mention these three leading schemes, and note the use of a modified form of UDC in the library of the Royal Pharmaceutical Society (London). A specific study on the adequacy of the NLMC for organising pharmacy books has been reported (Lopez-Mertz 1997). It is likely that these classifications will remain, for the foreseeable future, the default method for the organisation of pharmaceutical collections.

Both of these early guides mention the National Library of Medicine's Medical Subject Headings (MeSH) vocabulary as the main tool of detailed indexing of pharmaceutical literature, and it retains that status today. The thesauri for the *Biological Abstracts* and the *Excerpta Medica* bibliographic databases also cover pharmaceutical material in detail (Powell 1980, Blair 1980, Briggs and Crowlesmith 1995, Snow 1991, Snow 2008, Excerpta Medica 2008).

Examples of more subject-specific equivalents are the thesauri used in the indexing of the *International Pharmacutical Abstracts* (van Camp 1984, Snow 2008) and the *Derwent Drug File* (formerly *RINGDOC*) literature databases (Bawden and Devon 1980, van Putte 1990), and the thesaurus maintained by the UK Medicines Information Pharmacists Group, and used for indexing that group's medicines information resources, particularly the Pharmline bibliographic database on pharmacy practice and clinical use of drugs. Specialised thesauri are also used to index material in the *Martindale* pharmaceutical reference resource (Anon. 1984, Snow 1988, 2008), and the 'drug pipeline' databases, such as Adis R and D Insight and Pharmaprojects, noted below (Snow 2008).

There are numerous examples of special purpose pharmaceutical vocabularies and taxonomies. Terminologies derived for regulatory purposes and for pharmacovigilance (WHO-ART, COSTART and MedDRA) have been noted above. Another example is the taxonomy used to organise material in the British National Formulary (produced jointly by the Royal Pharmaceutical Society and the British Medical Association) and also materials in the guidelines from the UK National Institute for Health and Clinical Excellence. Unique identification codes for all pharmaceuticals available in each country are widely used (Snow 2008): a study has shown considerable inconsistency in the application of these codes in the USA (Guo et al. 1998).

Thesauri and classifications have been created by a number of pharmaceutical companies for the indexing of in-house databases: as an example, see Leitmeyer and Gillum (1993). The more recent tendency has been to adopt standard publicly available vocabularies for this purpose: see Harrison (1992) for an example of the adaption of the Excerpta Medica thesaurus for an in-house file.

The process of indexing pharmaceutical material, and the particular difficulties for the indexer, have been discussed, for the indexing of books and journals (Gibson 1983), of abstracting and indexing services (Barber et al. 1988), and of in-house bibliographic databases (Abbott 1997).

Pharmaceutical information sources, services and retrieval

There are various ways in which information resources may be categorised, so that an extensive set of diverse resources, as certainly exists for the pharmaceutical domain, may be better understood and organised (Robinson 2000, Bawden and Robinson 2001). There are four common, and general, typologies:

- by subject
- by format
- by location
- by type of material

To these, we might add further categorisations: by date, language, intended audience, and so on.

Previous resource guides have used some or all of these, generally in combination.

Andrews (1986) has a separate three-fold categorisation: by subject, e.g. 'pharmacology and toxicology', by type of material, e.g. 'pharmacopeias and standards', and by format, e.g. 'databases'.

Strickland-Hodge, Jepson and Reid (1989) categorise resources by type of material, e.g. 'bibliographies' and "textbooks' and monographs', with some elements of format, e.g. 'online databases and directories'.

Pickering (1991) offers a categorisation mainly by subject, e.g. 'toxicology and drug metabolism information', with some elements of type of material, e.g. 'intellectual property', and a separate categorisation by location, e.g. 'information needs and availability in the United States'.

Shields and Lust (2006) in the drug information resources chapter of the monograph edited by Malone, Kier and Stanovich (2006) make a partial distinction into primary, secondary and tertiary, but mainly use a rather subject-based categorisation, e.g. 'general product information', 'geriatric dosage recommendations', and 'pharmacy law'.

Snow (2008) also notes the categorisation of scientific literature sources as primary, secondary and tertiary, but again primarily categorises resources by their general subject, e.g. 'adverse reactions and drug interaction', or purpose, e.g. 'drug identification'.

Bawden and Robinson (2001) have categorised pharmaceutical information resources by a three-fold framework for type of material, denoting resources as:

- primary: the 'original information'
- secondary: value-added information, from some organisation of primary material
- tertiary: materials pointing to, and aiding the use of, primary and secondary materials

It is possible also to consider 'zeroth' order information, raw information before it enters the communication chain, for example the output from laboratory instrumentation. While such information is certainly vital in the scientific and clinical investigation of pharmaceuticals, it is not discussed here, as it does not constitute a generally available resource.

Similarly we may consider quaternary information resources, giving access to resource listings at a high level: 'bibliographies of bibliographies' and 'lists of lists' . A medical example of a 'list of lists', current at the time of writing, is Hardin MD (http://www.lib.uiowa.edu/hardin/md). Other examples of quaternary resources are lists of guides to literatures, such as that offered in chapter 4 of Snow (2008), and the PINAKES list of Internet subject gateways.

The Internet even offers quintenary resources: 'lists of lists of lists'. These higher level resources are not usually subject specific at the level of pharmaceutical information, and so will not be considered here.

We can now consider, in outline, pharmaceutical resources in this three-way categorisation. For more detail, see Bawden and Robinson (2001), which lists pharmaceutical resources of importance at that date , and includes resource listings for industrial research information services, and for health services medicines information.

For virtually all these resources, the period 1980 to date has seen a general move from print-on-paper to online and CD-ROM formats, and then to web-based delivery. Because of the scientific, medical and economic importance of this kind of information, particularly to the pharmaceutical industry, particularly those regarded as 'value added', have been relatively costly to use. This has led to a consistent demand for free or low-cost resources, especially for public-sector needs (see, for example Cooper 2008).

Primary resources

Because of its continuing importance, the journal literature is considered first in this section, followed by other forms of primary material.

Journals
Scientific and medical journals, now increasingly used in electronic form (Tenopir et.al 2003) remain a major resource, and have been so through the period from 1980, for all pharmaceutical information environments, whether as journal issues or separate articles (Baker and Jacknowitz 1981, Fong 1985, Gagnon 1986, Haygarth-Jackson 1987B, Okerson 1992, Cooper and McGregor 1994, Brown 1999, Ditchfield and Nielsen 2008). The newer routes of access to journal material, through open access preprint and e-print servers, are also used (Ginestet and Miranda 2002), although fully open access journals are still rare in this subject area (Clauson et al. 2008).

The range of journals of potential relevance to the topic is very wide, and the precise number difficult to determine. Sewell(1976) points out that as well as the core areas of pharmacy and pharmaceutical sciences, relevant material may appear in journals of medicine, the pre-medical sciences, chemistry, and even social science. Duckitt (1990) states that 'it is not possible to find a reliable figure for the number of journals in the fields which would encompass the full range of biological and medical biomedical interests within the pharmaceutical industry … a reasonable estimate must be around 10,000 titles.' Strickland-Hodge, Jepson and Reid (1989) list 220 journals of direct relevance to pharmacy, including 5 medical journals and 34 review journals; they encompass journals in 21 languages apart from English. Other estimates for the number include: 318 'European pharmaceutical journals' (Bador, Picard and Locher 1994); 289 'European pharmaceutical journals' (Bador, Romdhane and Lafouge 2003); and 317 'pharmacy-focused journals' (Clauson et.al. 2008).

Bringing matters up to date, Ulrich's periodicals directory for 2009 lists 2717 journals under the 'pharmacy and pharmacology' heading, and 23,935 under 'medical sciences'. The library of the Royal Pharmaceutical Society (London) has a collection of over 250 printed journals in pharmacy, pharmacology, pharmaceutics and medicine, and over 2000 e-journals in biomedical science. It can therefore be reasonably assumed that the journal literature of the subject consists of a core of about 300 titles, but with a scatter through a very wide selection of other material. Gorraiz and Schloegl (2008) reported a bibliometric analysis of the top-ranking journals of the area, focusing on the top-100.

Not all pharmaceutical journals are equivalent in nature. Strickland-Hodge, Jepson and Reid (1989) distinguish three kinds: scientific journals; those concerned with a specific kind of pharmacy, e.g. retail, which might be termed 'trade' journals; and those journals aimed at members of local professional associations or societies, which may have the character of newsletters. These 'local' journals have evoked some controversy. As long ago as 1971, it was being argued that they should transform themselves into newsletters, and give up the 'pretence' of journal status (Provost 1971); yet 20 years later, it was shown that some were more widely read and valued than higher status journals (Grussing and Wilkins 1991).

This leads into to other issues. Such journals rely greatly on pharmaceutical industry advertising for viability. The ethics of allowing such advertisements, and the related question of the publishing of articles from industry sources, has been controversial; for a flavour of the arguments, see Williams (2007), Smith (2003, 2007), and Irving (2005).

The content of local journals may be partly or wholly in languages other than English. Although this is increasingly regarded as the *lingua franca* of drug information, Strickland-Hodge, Jepson and Reid (1989) listed journals in 22 languages among their 220 pharmacy-related journals. A significant 'language barrier' affecting the use of information from non-English sources has been identified among pharmaceutical research workers (Thorp et.al. 1988).

With increasing volumes of literature, abstracts of journal articles become more significant as a time saving aid to literature searching. A study of one year's issues of seven pharmacy journals showed 60% of the abstracts to have omissions or inaccuracies (Ward, Kendrach, and Price 2004).

The pharmaceutical journal literature has been used for bibliometric analysis to analyse the literatures of drugs and drug classes (Bordons, Bravo and Barrigon 2004, Lopez-Munoz et al. 2003. Windsor 1975), to attempt to predict clinical success of drugs (Windsor 1976), and to analyse the research performance of pharmaceutical companies (McMillan and Hamilton 2000, Gambardella 1992, Narin and Rozek 1988, Koenig 1983),

Other primary resources

Report series may offer an alternative form of primary publication, especially from government departments and agencies, and from international organisations, while academic theses, dissertations and project reports may provide detailed information which does not appear in the literature (Duckitt 1990). Again, the influence of the web can be seen in making access to these various forms for 'grey literature' easier.

Patents, as noted above, in addition to their importance for competitor intelligence, and for legal and intellectual property issues, can provide scientific information not available elsewhere, although the reliability of the information contained in them may be questionable (Duckitt 1990, Hogan and Scarborough 1996, Eisenschitz 1991, Norton, 1982). Bibliometric analysis of the patent literature has been used to attempt to predict the clinical success of drugs in development (Windsor 1979).

Conference proceedings may provide information which never appears in the journal literature, or only at a later stage (Duckitt 1990); to meet this need, conferences reports databases are commonly provided by 'drug pipeline' information suppliers, for example IDdb Meeting Reports (Snow 2008). Even announcements of forthcoming conference papers can be valuable for current awareness and competitor intelligence. Providing advanced notification of meetings and conference, using announcements in journals and in specialist publications, used to be a common task for pharmaceutical information units (Forward and Selby 1978); web-based communication has now largely taken over this function.

News media of all forms provide information particularly relevant to commercial, regulatory, and competitor aspects, though medical and scientific matters also appear here. Conventional news sources are relevant, with web feeds, and the use of consolidating services such as Reuters Health (Jenkinson and Kane 2005), replacing the scanning of printed newspapers, which was common in the past. Specific pharmaceutical news sources, in particular the Scrip / Pharmaceutical and Healthcare Industry News Database service, are also widely used (Snow 2008, Brown 1994, Chang et.al. 1991).

For regulatory and legal purposes, access to legislation, regulations, standards, good practice guidelines and so on, and to the frequent updates of these, is essential.

Information about organisations, including company reports, and about individuals is now widely available through corporate and personal websites, replacing the files of paper brochures and contact lists, kept in the past by many information services (Duckitt 1990, Wisniewski 1998, Snow 2008).

Mailing lists, newsgroups, forums, blogs and other internet communication media are used for scientific and medical purposes – and their archives may be searchable, and valuable sources of specific information – but are of particular use in monitoring the views of the general public, and of support groups for particular diseases (see, for example, Savino and Shick 1998, Meier et.al. 2009, Rimer et.al. 2005, and Boulos and Wheeler 2007).

Publicly available information from the manufacturers of medicines, particularly the data sheets and patient information leaflets required by law to be produced in a standard format, are the fundamental source of information of each medicine. They are usually available as compendia or compilations for all the medicines available within a country; in the UK, for example, such compendia have been provided by the Association of the British Pharmaceutical Industry (Anon 1987), while in the USA they are made available through the National Library of Medicines 'Daily Med' service..

Not publicly available, but of importance within organisation and also required for regulation, is the internal information produced in the process of drug discovery, development and clinical trials, and both research and medical information services in the pharmaceutical industry need access to this. One specific example is the indexing, retrieval and (more recently) digitisation of laboratory notebooks and similar research documentation (Cibbarelli, Tenopir and Ott 1978, Samuel 1997, Hentz 2002, Le 2003, Caporizzo 2008). Increasing pressure towards openness and transparency in the drug development and licensing process has led to some companies making the results of clinical trials publicly available through the web, including 'negative' results not published elsewhere.

Secondary resources

In this section, we deal only with publicly available secondary sources; in-house databases have been dealt with above. Nor can we deal in detail with the many resources, particularly web resources, aimed primarily at the general public and consumers of medicines, and often of dubious quality: for reviews, see Kelley and Chae (2000), Perkins (2001) and Perdue and Piotrowski (2004).

Secondary sources are considered under the three headings of databases, reference services and databanks, and sources for summarised knowledge, with a final section on specialised searching facilities.

Database services

Bibliographic abstracting and indexing services for the relevant scientific disciplines have been a mainstay of pharmaceutical information provision through out the period. The sector has been such an important user of these services that it has considerably influenced their development.

The seven most important such services were all noted by Sewell (1976) and remain predominant over thirty years later (Snow 2008):

- International Pharmaceutical Abstracts
- Chemical Abstracts
- Biological Abstracts / Biosis
- Index Medicus / Medline / PubMed
- Excerpta Medica / Embase
- Toxline / Toxcenter / Toxnet
- Science Citation Index / Web of Science

These have been the subject of many comparisons and evaluations, for their value in providing pharmaceutical information: see, for example, Simkins (1977), Snow (1982A, 1984),

Kruse (1983), Bawden and Brock (1985), Sayers, Joice and Bawden (1990), Barillot, Sarrut and Doreau (1997), Biarez et.al. (1991), Sodha and Amelsvoort (1994), Fishman, Stone and DiPaula (1996), Brown (1998), Robinson et al. (2000), and Flory (2002).

Comparative evaluation of these sources, together with the specific pharmaceutical information sources noted below, have usually concluded that, although one or the other may be preferred for particular searches, a combination is usually needed for effective retrieval. Variations in coverage and indexing have consistently subverted the desire of database producers to offer 'one stop shopping' for pharmaceutical information.

The *Excerpta Medica/Embase* database has tended to be particularly favoured for good retrieval because of its responsiveness to the need for detailed pharmaceutical indexing (Powell 1980, Snow 1991, Brown 1998, Hallam and Plaice 1999). This kind of consideration has led to the creation of a number of databases specifically for pharmaceutical material, most notably Derwent's *Ringdoc* (latterly *Derwent Drug File*) database,with specific coverage and detailed intellectual indexing from several pharmaceutical perspectives (Bawden and Devon 1980, Hoover 1981, van Putte 1990, Burcham 1992). Other pharmaceutical specific bibliographic databases include the Iowa Drug Information Service (Hall and Foy 1983, Cornall et.al. 1981, Milne 1978, Rumschlag and Howes 1993)) and Pharmline, produced by the UK health service medicines information service (Rodgers 1985, Judd 2001).

Chemical information sources and systems, such as Beilstein and CAS/SciFinder, are important in the pharmaceutical area, particularly for drug discovery and development, as with any chemical research environment (Arisumi and Turner 1996, Bremner, Castle, Griffith, Keller and Ridley 2002).

The importance of competitor intelligence information, noted above, reflects the need, of a kind unique to the pharmaceutical sector, for an awareness of drugs in the 'pipeline' from discovery through development to clinical trials and marketing (Snow 2008, Breton 2003, Parkar and Toeg 1999). Numerous database services have been developed to meet this need, originally provided as index card files (Bottle and Linton1971): examples are Pharmaprojects, Adis R and D Insight, IMS R and D Focus, Prous Ensemble, Derwent's World Drug Index, the MDL Drug Data Report, and the Investigational Drugs Database (Snow 1993, 2008, Mullen et.al. 1997, Cheeseman 2002, Fenton and Hutton 1993, Blunck et.al. 2003). These are typically structured by drug substance, and provide 'value added' evaluated and summarised information. Studies have shown that there is little overlap between their content (Snow 2008); as with the bibliographic databases, a combination of sources is needed for comprehensive information collection. Sources of this kind, more than others, have undergone a constant process of rapid development, renaming, consolidation and changes of ownership.

Patents information is, as noted above, of considerable and continuing importance. It may be found in several disciplinary databases (Snow 1989) in general patents services (Oppenheim 1981), and also in sources specifically for pharmaceutical patent information (Johns et al.1 979, Gotkis 1992, Cheeseman 1995, Borne 1996).

Other types of secondary data sources designed specifically for pharmaceutical information include databases for carcinogenicity studies (McAuslane and Lumley 1993), for clinical trials details (Perkins 2007), and for pharmaceutical news compilations (Chang et.al. 1991).

Reference collections and data banks

The copious amounts of structured data associated with the use of medicines has resulted in the availability of an array of reference tools. These range from small-scale reference books, for example a local formulary for use in a hospital, to extensive databanks, and include sources for complementary and traditional medicines (Lapidus and Bond 2008). Originally in printed form, virtually all have now migrated to digital form, or to multiple print and digital format (Woodward 1995, Gretz, Stadler and Thomas 1996), and some to mobile devices (Galt et al. 2005, Barrons 2004, De Groote and Doranski 2004, Gora-Harper and Amerson

2006). Snow (2008) recommends acquisition of the print version of major resources, to complement their digital equivalents. She also points out the value of retaining older copies of printed resources of this kind, as they may contain detailed information which has been omitted from more recent editions, and cannot otherwise be found: this point was demonstrated in a detailed comparison of secondary and tertiary sources (Bawden and Brock 1982).

The most numerous types of such resources are pharmacopoeias, formularies, handbooks, drug information bulletins, drug dictionaries, and similar quick-reference tools, many of which are national or local in nature. Lists, descriptions and comparisons of the more widely-applicable resources of this type are given by Snow (2008), Shields and Lust (2006), Bawden and Robinson (2001), Andrews (1986), Strickland-Hodge, Jepson and Reid (1989), Smith (1996), Olssen and Pal (2006), and Hartel and Kuferberg (2004).

Important examples, which have retained their place throughout the period of this review include *Martindale's Extra Pharmacopoeia* (in print, now including digital versions, since 1883), the *Physician's Desk Reference* (US), the *Merck Handbook*, the *Index Nominum* drug name dictionary, and national drug lists, such as, for the UK, the *British National Formulary*, the *electronic Medicines Compendium*, and the *Monthly Index of Medical Specialities (MIMS)* (Royal Pharmaceutical Society 1996, Fijn et al. 1999, Fowler 2001, Fryer, Baratz and Helenius 1991, Snow 1988, 2008, Wills 1986). Similar resources are available for veterinary medicines (Snow 2008).

These sources were invariably listed as commonly used tools in the studies of health professionals' information behaviour noted above.

Evaluated and summarised knowledge sources

A third important category of secondary sources of pharmaceutical information is that of those sources which provide evaluative summaries of the knowledge base.

An important source for this, throughout the period covered, is the review article, providing a critical evaluation of the literature, and typically published in a specialist 'review 'journal'. These are numerous for pharmaceutical information: Sewell (1976) notes that "review publications occur in practically every area with which the pharmacist is concerned". One could say the same for the pharmacologist or medicinal chemist, so that these resources retain their traditional importance (Sayers, Joice and Bawden 1990).

A specific form of literature evaluation article is the systematic review, geared to providing explicit advice on evidence-based best practice in an aspect of healthcare; these may be found from 'general' bibliographic secondary sources, or through specialist sources for evidence-based practice, such as the Cochrane Database of Systematic Review (Fitzpatrick 2000, Koonce, Giuse and Todd 2004). In turn, these feed into health service guidelines, which incorporate the reviewed literature (Moores 2006, Linden et al. 2007), and into public information guides (Dolovich et.al. 2006).

Encyclopaedias, monographs and textbooks form another class of resource for presenting evaluated pharmaceutical knowledge. The latter, typically named after their originator, and often running through many editions, generally now have both digital (online and/or CD-ROM) and printed versions; Snow (2008) gives a detailed listing. Well-known examples are: *Goodman and Gilman's 'Pharmacological Basis of Therapeutics'*, in its 11th edition in 2005; *Myler's 'Side Effects of Drugs'*, in its 15th edition in 2006; *Stockley's Drug Interactions*, in its 8th edition in 2007, *Remington's Science and Practice of Pharmacy* in its 21st edition in 2005, *Rang and Dale's Pharmacology*, in its 6th edition in 2007, and *Burger's Medicinal Chemistry and Drug Discovery*, a multivolume work with its 6th edition published between 2003 and 2008. A newer, though arguably equivalent type of resource is a specialised, and usually proprietary, web portal, providing knowledge summaries in a particular area, with links to related resources: an example is Elevier's xPharm service supporting drug discovery (Saimbert 2006).

Specialised searching facilities
The sources noted above have, between them, generated a number of unusual searching facilities. In some cases, these remain unique to the pharmaceutical situation; in others, they have been pioneered here, but become more widespread. They include:

- chemical structure and substructure searching, similarity matching, and macromolecular sequence searching (Ash, Warr and Willett 1991)
- searching features allowing for the multiple nomenclatures and terminologies used for medicinal substances (Kremin 1979, Snow 1992, 2008)
- automated assistance for query formulation in databases with complex terminologies (Oakes and Taylor 1998)
- searching specifically for medicines dispensed in other countries, with unfamiliar names, uses, and standards (Snow 1982B, 2008)
- retrieval of the generic forms of chemical structure, so-called Markush structures, typically found in pharmaceutical patents (Kaback 1980, Lynch, Barnard and Welford 1981, Barnard 1991, Benichou, Klimczak and Borne 1997)
- identification and distinction of medicines with names which either look similar or sound similar (Lambert, Chang and Lin 2001, Kondrak and Dorr 2006)
- identification of unknown medicines, in capsule or tablet form, by searching on shape, colour, markings, etc., in systems such as TICTAC and Identidex, typically achieving 90% accurate identification (Snow 2008, Weaver, Hatton and Doering 2004, Raschke et al. 2003, Popa and Robertson 1994).

Tertiary resources

These resources, which point to, and aid the use of, 'lower order' materials, have increased in number for the pharmaceutical domain over the period of this review, due in large part to the influence of the Internet.

One type of such resources which have retained their importance over the period is the subject guide, examples of which have been discussed in an earlier section.

Another is the 'directory' type of resource, providing structured and summarised information and data on pharmaceutical companies, research organisations, sales, markets, and so on. Most of these publications are now presented on the web, with some integrated into pipeline database services; Snow (2008) gives numerous examples.

The new type of tertiary resource which has proliferated with the Internet is the annotated list of sources, often packaged as a 'portal'. These have been created in a number of formats:

- public Internet portals for pharmaceutical information, such as Pharmweb, the Virtual Library of Pharmacy, and Martindale's Virtual Pharmacy Center (Snow 2008, De Manuele 1998)
- public Internet portals for more general scientific information, including pharmaceuticals, such as the UK BIOME portal (MacKay 2005, Gray 1999)
- portals created by information producers to integrate their pharmaceutically relevant sources and services. These include both commercial providers, such as Thomson Pharma (Felter 2005, Plosker 2006) and public bodies, such as the US National Library of Medicine (Knoben et al. 2004)
- in-house proprietary portals and intranets, integrating internal sources and services (see, for example, Srodin and Struplczewski 2002, Little and Millington 2001)

Pharmaceutical information and knowledge management

As has been seen above, the pharmaceutical industry, government regulatory agencies and health services are all voracious producers and consumers of information. Naturally enough, the pharmaceutical domain has been the source of many innovations in information and knowledge management techniques and systems, including the management of documents and records, so as to make productive use of this plethora of information.

Some illustrative examples of these innovations are given below, roughly categorised by topic. General strategic approaches to information management have been described, varying in their applicability from a single pharmaceutical company (Huotari 1995) to the UK pharmaceutical profession (Anon 1997).

Information technology and information systems

The pharmaceutical area has been a major innovator and driver in this respect, the pharmaceutical industry in particular (see, for example Lamb, King and Kling 2003, Bruque-Camara, Hernandez-Ortiz and Varga-Sanchez 2004, and Schwartzer 1995). Specific examples of technologies include database construction (Dugas et al. 2003), enterprise resource planning systems (Spremic and Vuksic 2005), the provision of portals and intranets (Little and Millington 2001, Srodin and Strupczewski 2002), and data warehousing (Alshawi, Irani and Saez-Pujol 2003). Information technology has always played a major part in supporting the activities of pharmaceutical libraries and information units (see, for example, Benfield, Haraki and Venkataraghaven 1981 and Weaver and Porter 1991). This environment has in turn contributed to the information systems field, for example by the development of methods for 'user sensitive' systems implementation (Goodman 1998).

Libraries and document delivery

The provision of documents through libraries has always been a major part of pharmaceutical information management. The industry has been a major user of, and innovator in, document supply services, particularly as the environment changed to mainly digital provision (Delaney 2003, Cooper and McGregor 1994, Haygarth-Jackson 1987B, Sherwell 1989, Stadler, Mernke and Thomas 1999, and Karasab 2006).

Industry libraries have also been innovative in the provision of library services in general, particularly those taking a 'pro-active' stance in information provision (He, Chadhuri and Juterbock 2009). The optimal way of providing current awareness services, initially based on printed library materials, and latterly on electronic sources, has been a perennial concern (Blick and Magrill 1975, Blick Gaworska and Magrill 1982, Hodge and Walker 1984, Law 1989, McIntosh 1993, and Hentz 1996). Other innovations have concerned reference services (Delaney 1999), maximising use of the journal collection (Archer 1997), and collection development (Thorpe 1979, Law 1989). Academic pharmaceutical libraries have also pioneered techniques for multifaceted collection evaluation (Bergen and Nemec 1999).

Pharmaceutical libraries have been leaders in the move away from solely print resources, first to microforms (Blick and Ward 1984), and then to digital resources (Gretz, Stadler and Thomas 1996, Brown 1999), with development of a 'pharmaceutical model' for the licensing of electronic journals (Ditchfield and Nielsen 2008). Many pharmaceutical industry libraries were largely or wholly digital by the end of the period reviewed, with hard-copy, if retained at all, moved to external stores.

Developments in library automation systems in pharmaceutical settings (Zolezzi 1991, Hentz 1994, Zom and Marshall 1995) have led to the development of digital or hybrid libraries. This has come about in stages: from delivery of materials to users desks (Hoskin, Lister and Marsh 1982), through provision of workstations in largely print-based libraries (Schulte 1986), and then parallel physical and virtual libraries (Sherwell 1997A, 1997B, Ward and Warr 1998), to the fully digital library (Archer 2004).

Facilitating users

The pro-active services noted above led, particularly in industry, to the introduction of what was termed 'end-user searching', by which scientists and clinicians were encouraged to undertake their own searching in computerised sources: online bibliographic databases

(Haygarth-Jackson, Holohan and Shether 1978, Leipzig, Kozak and Schwartz 1983, Marshall and Zorn 1997), CD-ROM bibliographic databases (Mullan and Blick 1987, Whittall 1989), and specialised chemical information sources (Leipzig, Kozak and Schwartz 1983, Warr and Haygarth-Jackson 1988). This emphasis on 'empowering users', pioneered in pharmaceutical settings and widely followed elsewhere, has led to pharmaceutical information services taking a largely consultant / advisor / faciliator stance, replacing the intermediary role (Goodman and Boyce 2001, Goodman, Whittall and Morrison 2001).

Document management

The information intensive nature of drug development and use leads to extensive document production, particularly at the regulatory stage (Dobbs 1993, Ehrhard 2003, Zimmer 2003, Hoefer et.al. 2002), though also for R and D documentation (Samuel 1997). Systems designed for the creation and management of paper documentation have been extended to deal with digital documentation. Pharmaceutical companies were among the first users of large-scale electronic publishing (Wasserman 1990, Warr 1991, May 1995), and electronic data capture (Grossman and Bates 2008), and to link such systems to documentation management processes (Lander 1998). With increasing use of digital documents, specific measures for their preservation and archiving has become an important issue (Anon 1992, Stephens 2000, Stamatoplos 2005). The practices of systematic document and records management, including file organisation, were introduced at a relatively early stage and are of increasing importance (Chalmers 2001, Curran and Sundar 2002), with records management in particular identified as a significant component of information management in the pharmaceutical sector (Goodman 1994, Samuel 1998). Quality control and confidentiality of data sources has been a major issue (Chalmers 2001, Pierredon 1995, Ham 1995), as have records management issues resulting from company mergers and restructuring (Marsh 2000). The historical records of the pharmaceutical industry have also been noted as an archival resource worth preserving (Stevenson 1997).

Knowledge management

The pharmaceutical industry has been a leader in the transformation of library/information services from fulfilling largely a traditional role of provision of external published information to one placing equal importance on internally generated information. The practice of knowledge management as a means of maximising the value of internal information and knowledge has been promoted widely within the pharmaceutical industry, though meeting a mixed reception and some scepticism (Collins, Shaw and Billington 1999, Liebowitz 2000, Curry and Kerrin 2004, Wang 2006, Pappa, Stergioulas and Telonis 2009). Practical solutions for knowledge sharing, involving both face-to-face facilitation and technical solutions, have met with the best acceptance: see, for example, Robson, Bandle and Ince (1999), Hynes et al. (1999), Hoffman, Pallansch and Shafer (2000), Duffy (2000), Roth (2003), Evans and Brooks (2005), and Styhre et al. (2008). The idea of 'knowledge integration' as a form of knowledge management has also been influential (Abbott 1998, 2004, Millington and Walker 2003). Other approaches to the sharing and management of pharmaceutical knowledge have included peer review of information (Bergquist, Ljungberg and Lundh-Snis 2001), structured writing (Bernhardt and McCulley 2000), and integrated learning (Riedinger 2008).

Quality issues

The pharmaceutical environment is one of the most heavily regulated, and controlled by codes of practice affecting many aspects, from the research laboratory to the community pharmacy. Good Clinical Practice, Good Laboratory Practice, Good Manufacturing Practice, and others, have all had considerable information implications (Smith 1997, Rammell 1997, Chalmers 2001, Olson 2001, Le 2003, Lee and Lee 2006), as have the industry's own codes of practice for the promotions of medicines (Simmonds 2001).

Not surprisingly therefore, pharmaceutical information providers in all environments, but particularly in the industry, have sought to apply quality principles to their activities. This has been particularly so in medical information departments, where a variety of quality mechanisms have been used, especially in response to ISO 9000 certification (Khan and Bawden 2000). These include standardised and documented procedures and guidelines, including objective quality measurements (Davies 2001, Robson and Riggens 2001, Curran and Nowakowski 1994, Curran, Sundar and Westhe 2003), as well as more elaborate

procedures such as benchmarking and organisational maps (Kinnell 1997, Trzan-Herman and Kiauta 1996). Wormleighton and Leighton (2009) describe a audit of the medical information provision in the various national affiliates of a multinational pharmaceutical company. Outside the industry, standardised procedures have been recommended to pharmacists in providing drug information since the 1970s (Kirkwood and Kier 2006), leading here also to a concern with more formal definitions of quality (Ninno and Ninno 2006).

Assessing value and impact

A consistent theme in pharmaceutical information management has been the evaluation of the value of information services, with a particular emphasis on cost-benefit; perhaps not surprisingly, in view of the resources invested in the area. A variety of methodologies have been explored, with an increased emphasis on objective measurement, very different from the time when it could be said that "service evaluation is highly subjective", dependent purely on expressions of user satisfaction (Brown 1983).

A number of early studies examined the cost-effectiveness of particular services in industry information units (Ashmole, Smith and Stern 1973, Blick 1977A, 1977B); although the methodologies used may no longer be regarded as appropriate, their pioneering nature may still be recognised. User surveys, to obtain qualitative understanding of the value of aspects of services have formed another standard approach (see, for example, Baker 1990, Hoffman and Gumbhir 1993, Bauman and Bettenhausen 1994, and Albano and Santhouse 2003). More holistic approaches to service evaluation have used a mixed methods approach, linking cost analysis with user surveys and other means of assessing value of information systems and services (Ljungberg and Tullgren 1976, 1977, McElroy 1982, Saltzman 1995).

Some attempts have been made to provide assessment of the 'real value' or 'direct impact' of pharmaceutical information services. These have included the reporting of individual incidents of benefit (see, for example, Fingerote and Blanchard 1994) and the assessment of links between specific services and measurable impact: for example between the overall stated satisfaction of doctors with information provided by a pharmaceutical company and the prescribing of that company’s products (Albano and Santhouse 2003), and between the provision of drug information services in a hospital and reduced mortality rates (Pitterle et al.1994). Other approaches have been the identification of critical information needs (Huotari 1995) and of the contribution of information to company priorities (He, Chadhuri and Juterbock 2009), information mapping and auditing (Ellis et.al. 1993), and inter-company analysis of the relation between information environment and research productivity (Koenig 1990).

Influence on information science

The pharmaceutical information domain, because of its numerous and diverse users and sources, its technical advances, and its economic and social significance, has played a major role in advancing the discipline of information science itself.

First, and most obvious, is the issue of information technology. Shepherd (2001) notes the applications of developing technology for delivering pharmaceutical information in health services, including microfiche, electronic publishing, CD-ROMs, online services, the Internet and latterly Internet portals, and health service intranets. As shown above, the pharmaceutical sector has always been in the forefront of applications in information technology to information communication: from pre-computer documentation technology (Bird 1976), to the digital computer (Lewi and Braet 1970, Haygarth-Jackson 1977, Blakeman 1985) and online searching (Blick and Magrill 1978, Haygarth-Jackson, Holohan and Shether 1978, Goodemote 1980, Bawden 1986), to the personal computer (Rudin, Hausele and Stollak 1995, Bawden 1988), to CD-ROMs (Whittall 1989), the Internet (Anon 1996) and Web 2.0 (Warr 2008).

The case of online database searching is particularly cogent example. Bourne and Hahn (2003), give a number of examples of the pioneering role of the pharmaceutical industry in the development of online services. The first paying subscriber to the SDC service, itself the first to emphasise online biomedical databases, was the Pfizer pharmaceutical company library, and the sector provided more than half the service's users for its first few years of operation.

Nor is it shaming to note pharmaceutical involvement in the development of information technologies which never really made their mark, from television as a medium for conveying medicines information (Springer et al. 1978) to the short-lived videotex (Hull 1994). It is also worth remembering that the idea, now taken for granted, of users doing their own searching in digital resources was pioneered in this sector.

Second there is the influence of the pharmaceutical sector on the information industry. This is seem at the micro-level in the effect of the 'big users', particularly in industry, on the development on the online, and latterly CD-ROM, sector, in influencing the development of the disciplinary databases, and the creation of the pharmaceutically-specific services. Associations of pharmaceutical information users - particularly the the Pharma Documentation Ring (PDR) (Di Nallo and Schopfel 2008), but also the Association of Information Officers in the Pharmaceutical Industry (AIOPI), recently absorbed into the Pharmaceutical Information and Pharmacovigilance Association (PIPA), in the United Kingdom - have been particularly important in this respect. On a larger scale, several significant information industry companies have developed largely to serve this sector: for example, the Institute for Scientific Information (Garfield 2001, 2008), Derwent Publication (Poynder 2000) and Prous (Mason 1999).

Third there is the sector's influence on research and development within information science itself, the pharmaceutical sector being the locus for much practitioner research, sadly absent from most of the information world (Blick 1983). The most obvious example is the development of chemoinformatics, which was to a great extent stimulated and promoted by the pharmaceutical industry (Chen 2006, Willett 2008). Another is the development of the user-oriented and contextualised style of comparative database evaluation noted above, and promoted by pharmaceutical sector collaboration (Bawden 1980). Yet another is the pioneering work, again noted above, on the assessment of the value and impact of information services, latterly taken up in other parts of the library / information world. Other examples where research techniques pioneered or developed in the pharmaceutical domain have been taken up more widely include data mining and text mining (Banville 2008, 2009, Bremner, Castle, Griffith, Keller and Ridley 2002, Olaleye and Tardiff 2001), and the use of bibliometric analysis to make scientific and commercial predictions (Windsor 1976, 1979). Finally, the development of the many and varied pharmaceutical classifications, thesauri and other terminologies, described in an earlier section, has influenced theory and pract
ice in information organisation generally.

In these various ways, the pharmaceutical sector has influenced the developing principles and practice of information science over the period of this review, and has provided career opportunities for many information scientists (Alberts 2008, Crawford and Carter 1986). [Indeed, the authors of this review both began their information careers in this sector, as a trainee information officer in pharmaceutical research, and as an abstractor for Derwent's RINGDOC service respectively.]

Windsor (1999) has argued that the roots of the information science discipline itself are to be found in industry, and specifically in the pharmaceutical industry. The outline of the pharmaceutical information environment over three decades, presented in this review, suggests that this view has much to recommend it.

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